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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: CAS Medical Systems, Inc.

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Prepared: October 2, 2006

Trade Name: CAS 750E Series Monitor

Common Name: Multi-Function Patient Monitor

Classification Name: Oximeter (74DQA)

EQUIVALENCE

The CAS 750E Series Monitor, with NIBP modification for ECG synchronization (gating) and Mean Heart Rate Deviation Measurement Trigger is equivalent to the following device:

- CAS 750E Series Monitor (K051896)

DESCRIPTION

The CAS 750E Series Monitor, with ECG Synchronization and Mean Heart Rate Deviation Measurement Trigger is a modification based on the existing 750E monitor. Only the 750E non-invasive blood pressure (NIBP) module portion of the multiparameter monitor is affected by the change. All other parameters of the 750E (Sp02, respiration rate, EtC02 and temperature) remain untouched. The individual module responsible for NIBP is called ND+.

ECG Synchronization can use an ECG (R-wave) input signal to time correlate the occurrence of a cardiac contraction with the detection of the oscillometric blood pressure pulses occurring in a cuff wrapped around the patients upper arm. ECG Synchronization is available only when the ND+ module is operating in adult mode.

ECG synchronization is taken from the edge of the ECG R-wave synchronization input signal. The delay between the subjects actual R-wave and the edge of the ECG synchronization pulse is user definable through software. This delay can be defined to be from 0 – 80ms in increments of 1ms. Once set this delay must remain constant (± 5ms) throughout the blood pressure measurement.

If during the NIBP measurement the ECG synchronization input stops providing pulses at a rate equal to 25 beats per minute (BPM), the ND+ module will stop using the ECG synchronization pulse to time correlate cardiac contractions with the detection of the oscillometric blood pressure pulses and complete the blood pressure measurement using only the oscillometric technique.

On power-up and following a reset, ECG synchronization is disabled.

The Mean Heart Rate Deviation Measurement Trigger functions while in the automatic interval measurement mode and with an ECG synchronization input present. In this mode, the Mean Heart Rate Deviation Measurement Trigger can be enabled to initiate an off-cycle blood pressure measurement when a user defined change in the subject's heart rate is detected by the ND^{+} module for a period of approximately 10 seconds. The last NIBP pulse rate measurement is compared to the current heart rate. If the current heart rate exceeds the user defined threshold, for a period of 10 seconds, an off-cycle blood pressure measurement shall be initiated. At all times there will be a minimum time between NIBP measurements of 30 seconds. The start of the off-cycle blood pressure measurement shall restart the automatic interval timer

To produce an off-cycle measurement, the "user defined" changes can be any of the following:

- a fixed value change in the mean heart rate of the patient between 1 and 98 BPM;
- a percentage change in the mean heart rate definable within 1 to 98%;

The monitor, its equivalent and parameters:

Model(s)	Parameters (Variations)
750E-1 (750EM-1)	ECG, respiration and temperature, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-2 (750EM-2)	ECG, respiration and temperature & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-2MS, (750EM-2MS)	ECG, respiration and temperature & Masimo $Sp0_2$, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-2NL, (750EM-2NL)	ECG, respiration and temperature & Nellcor $Sp0_2$, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3MSC (750EM-3MSC)	ECG, respiration and temperature, Masimo Sp02, and EtC02, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3NLC (750EM-3NLC)	ECG, respiration and temperature, Nellcor Sp02, and EtC02, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3MS (750EM-3MS)	ECG, respiration and temperature, Masimo $Sp0_2$, & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3NL (750EM-3NL)	ECG, respiration and temperature, Nellcor $Sp0_2$, & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-4MS (750EM-4MS)	ECG, respiration and temperature, Masimo $Sp0_2$, EtC02 & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-4NL (750EM-4NL)	ECG, respiration and temperature, Nellcor $Sp0_2$, EtC02 & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).

750E Series Indications for Use

The 750E patient monitor is intended to continuously monitor a patients ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (%Sp02), respiration rate, temperature and end tidal carbon dioxide (C02). The monitor is designated as a bedside/portable monitor and is intended for use on adult, pediatric and neonatal patients in the care of health care professionals.

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Comparison of Technological Characteristics

The 750E Series Monitor (with modifications) is derived from the CAS 750E (K051896) with regard to form factor and general overall look. A number of identical components are found in both products, most especially the ECG, Respiration, End Tidal C02 (EtC02), choice of pulse oximeters; Masimo SET® or Nellcor® OxiMax®, temperature and NIBP. It is only the non-invasive blood pressure MAXNIBP® parameter that is modified.

The modification does not affect indications for us and the fundamental scientific technology of the predicate 750E Series Monitor.

Nonclinical Performance Testing to Show Substantial Equivalence

The predicate model 750E has received a full suite of in-house and third party testing. All are determined to remain valid for this modification. The list below represents the additional V&V testing to assure functionality of the modification.

VP/VR 050041	750 w/ ND+ ECG Gating HR Deviation Verification Plan	Evaluate the DSP and ND+ software in the model 750 monitor	All pass
VR/VP 060059	750 V2.31 w/ ND+ECG Gating and HR Deviation Verification Plan	Evaluate the DSP software in the model 750 ND+ module for HR deviation functionality	All pass

Clinical Testing to Show Substantial Equivalence

The study referred to below represents clinical testing specifically related to the 750E modification.

ANSI/AAMI SP10	Adult/Pediatric Study of CAS Model 750 Non-Invasive Blood Pressure Monitor using "ND+" NIBP Module w/ECG Gating: AAMI SP10:2002 Format July 7, 2005	Long considered a consensus standard by the US FDA for this type of product. The clinical validation of the 750 monitor with the ND+ NIBP module w/ECG Gating was conducted at the Univ. Tennessee Medical Center.	Complies with SP10

Conclusions Drawn from Clinical and Nonclinical Testing

With the substantial testing of a non-clinical and clinical nature, it is the conclusion that the modified 750E is substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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CAS Medical Systems, Inc.
c/o Ron Jeffrey
Director, Regulatory Affairs
44 East Industrial Rd.
Branford, CT 06405

Re: K063087
Trade/Device Name: 75OE Series Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II
Product Code: MWI
Dated: October 4, 2006
Received: October 10, 2006

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

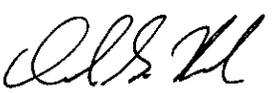
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K063087

Device Name: 750E Series monitor

Indications for Use: The 750E Patient Monitor is intended to continuously monitor a patients ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (Sp02), respiration rate, temperature and end tidal carbon dioxide (C02). The monitor is designed as a bedside/portable monitor and is intended for use on adult, pediatric and neonatal patients in the care of health care professionals.

Prescription Use __x___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063087